



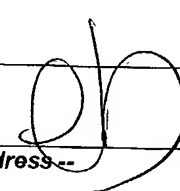
# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,417	12/04/2001	Philip H. Coelho	31120-pa	4542
37095	7590	09/13/2004	EXAMINER	
BERNHARD KRETEN, ESQ & ASSOCIATES 1331 GARDEN HIGHWAY SUITE 300 SACRAMENTO, CA 95833			BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/009,417	COELHO ET AL.	
	Examiner	Art Unit	
William H. Beisner	1744		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 9-15, 17-20, 22-27 and 53-55 is/are pending in the application.
- 4a) Of the above claim(s) 9-15, 22-25 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20, 26, 27, 53 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/4/01</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group III, claims 17-20, 26, 27 and 53, in the reply filed on 01 June 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 9-13, 22-25 and 54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01 June 2004.

### ***Information Disclosure Statement***

3. The information disclosure statement filed 04 Dec. 2001 has been considered and made of record.

### ***Claim Objections***

4. Claim 55 is objected to because of the following informalities: In the last paragraph of claim 55, "a thrombin receiving instrumentality communicating" appears to be missing a word such as "vessel" after "receiving". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

Art Unit: 1744

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 17, 18, 26, 53 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Coelho et al.(US 6,274,090).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

With respect to claim 18, the reference of Coelho et al. discloses a single donor biological glue processing device (10) that includes a thrombin processing means (40); a clotting and adhesive proteins processing means (60) operatively coupled (20) to the thrombin processing means (40); and means (2) for receiving plasma via the operative coupling (20).

With respect to claim 53, the reference discloses a thrombin syringe (42) ensconced in a bag (16) and a clotting and adhesive syringe (66) ensconced in a bag (68).

With respect to claims 17, 26 and 55, the reference discloses a device (40) for preparing thrombin from plasma that includes a reaction chamber (26) having a solution of CaCl<sub>2</sub> and ETOH therein (See Figure 3); means (24 and 18) for admitting plasma into the reaction chamber (26); a thrombin receiving syringe (42) coupled to the reaction chamber (26) and a filter (44) located between the reaction chamber (26) and the thrombin receiving syringe (42).

***Claim Rejections - 35 USC § 102***

7. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Hirsh et al. (US 5,643,192).

The reference of Hirsh et al. discloses a system of bags that are used form thrombin and clotting and adhesive proteins. Note the bags are operatively coupled with one another during the processing and are capable of receiving plasma from a blood collection bag (See the "Example").

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1744

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 19, 20 and 27 are rejected under 35 U.S.C. 103(a) as being obvious over Coelho et al.(US 6,274,090) in view of Cederholm-Williams et al.(US 5,795,571).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in

Art Unit: 1744

the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The reference of Coelho et al. has been discussed above.

Claims 19, 20 and 27 differ by reciting that the reaction chamber includes glass beads.

The reference of Cederholm-Williams et al. discloses that it is conventional in the art to employ glass beads within a reaction chamber used to convert prothrombin into thrombin in the presence of calcium so as to facilitate the removal of fibrin (See column 6, lines 12-31).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the reaction chamber (26) of the primary reference of Coelho et al. with glass beads for the known and expected result of facilitating the removal of fibrin during the conversion of prothrombin to thrombin.

12. Claims 26 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsh et al. (US 5,643,192) in view of Holm (US 5,603,845).

The reference of Hirsh et al. discloses adding calcium chloride and plasma within a (reacting chamber) such that the plasma is clotted to form thrombin and fibrin. The reacting chamber or bag includes a means for delivering plasma since plasma is added to the bag (See the Example)

Art Unit: 1744

While the reference discloses filtering the clotted plasma to remove fibrin with a filter, the reference is silent as to the use of a syringe for collecting thrombin that is connected to the reacting chamber via the filter.

The reference of Holm discloses that it is known in the art to collect a reaction product (100) between plasma (94) and a reagent (40) using a filter (66) between a syringe (46) and the reaction chamber (34).

The reference of Hirsh et al. also discloses that the collected thrombin when used is intended to be dispensed from a syringe device (See the Example).

In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a filter/syringe arrangement disclosed by the reference of Holm for the known and expected result of providing an art recognized means for collecting and filtering a blood reaction product which is required of the system and method of the primary reference.

13. Claims 19 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsh et al.(US 5,643,192) in view of Holm (US 5,603,845) taken further in view of Cederholm-Williams et al.(US 5,795,571).

The combination of the references of Hirsh et al. and Holm has been discussed above.

Claims 19 and 27 differ by reciting that the reacting chamber includes glass beads.

The reference of Cederholm-Williams et al. discloses that is it conventional in the art to employ glass beads within a reaction chamber used to convert prothrombin into thrombin in the presence of calcium so as to facilitate the removal of fibrin (See column 6, lines 12-31).



In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the reaction chamber (26) of the modified primary reference with glass beads for the known and expected result of facilitating the removal of fibrin during the conversion of prothrombin to thrombin.

14. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsh et al.(US 5,643,192) in view of Holm (US 5,603,845) taken further in view of Boros et al.(RO 105360).

The combination of the references of Hirsh et al. and Holm has been discussed above.

While the modified primary reference employs a  $\text{CaCl}_2$  reagent, claim 17 differs by reciting that the reagent includes both  $\text{CaCl}_2$  and ETOH.

The reference of Boros et al. discloses that it is known in the art to employ ETOH and  $\text{CaCl}_2$  during the formation of thrombin from plasma (See the English language abstract).

In view of this teaching, it would have been obvious to one of ordinary skill in the art employ both ETOH and  $\text{CaCl}_2$  during the formation and purification of thrombin for the known and expected result of providing alternative reagents known in the art for the formation of thrombin from plasma.

15. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsh et al.(US 5,643,192) in view of Holm (US 5,603,845) and Cederholm-Williams et al.(US 5,795,571) taken further in view of Boros et al.(RO 105360).

The combination of the references of Hirsh et al., Holm and Cederholm-Williams et al. has been discussed above.

Art Unit: 1744

While the modified primary reference employs a CaCl<sub>2</sub> reagent, claim 17 differs by reciting that the reagent includes both CaCl<sub>2</sub> and ETOH.

The reference of Boros et al. discloses that it is known in the art to employ ETOH and CaCl<sub>2</sub> during the formation of thrombin from plasma (See the English language abstract).

In view of this teaching, it would have been obvious to one of ordinary skill in the art employ both ETOH and CaCl<sub>2</sub> during the formation and purification of thrombin for the known and expected result of providing alternative reagents known in the art for the formation of thrombin from plasma.

### ***Double Patenting***

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 17, 18, 26, 53 and 55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-10 of U.S. Patent No. 6,274,090. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are anticipated by claims 2-10 of U.S. Pat. No. '090. Note the instant claims include the language comprising which does not preclude the presence of

additional structural elements. With respect to claim 26, it would have been obvious to separate the protein processing set from the thrombin processing set when the processing of thrombin is only required.

18. Claims 19, 20 and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-10 of U.S. Patent No. 6,274,090 in view of Cederholm-Williams et al.(US 5,795,571).

Claims 2-10 of U.S. Patent NO. '090 encompass a device that is substantially the same as that recited in the instant claims above.

Claims 19, 20 and 27 differ by reciting that the reacting chamber includes glass beads.

The reference of Cederholm-Williams et al. discloses that it is conventional in the art to employ glass beads within a reaction chamber used to convert prothrombin into thrombin in the presence of calcium so as to facilitate the removal of fibrin (See column 6, lines 12-31).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the mixing syringe of the patented claims with glass beads for the known and expected result of facilitating the removal of fibrin during the conversion of prothrombin to thrombin.

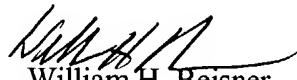
### ***Conclusion***

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

Art Unit: 1744

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB